Washington State Department of Health

ELABORATIONS

News and Issues for Washington's Clinical Laboratories

Volume VII Issue 8 September 2002

9th Annual Clinical Laboratory Conference

by Leonard Kargacin

The 9th Annual Clinical Laboratory Conference will be held on November 11, 2002, at the Seattle Marriott Hotel near Sea-Tac International Airport. This is an excellent opportunity to hear about the current status of health care from a variety of experts.

Dennis Weissman, President and Publisher of Washington G-2 Reports in Washington, D.C., will present the Keynote address for the Conference. This year's session is entitled **"National Policy Priorities & Trends for Laboratories: Taking Stock of the Midterm Elections"**. Those who have heard Dennis speak in the past know that his presentation will be very dynamic and thought provoking.

Michael Astion, MD, PhD, Associate Professor at the University of Washington Department of Laboratory Medicine in Seattle, will present a session entitled **"Laboratory Errors that Jeopardize Patient Safety".** His presentation will include a review of the major findings of benchmark population studies of patient safety in hospitalized patients and a framework for understanding the errors in clinical laboratory services most likely to jeopardize patient safety.

Rick Zimmer, Six Sigma Black Belt at Quest Diagnostics in Seattle, will present a session entitled **"Six Sigma: The Quality Improvement Breakthrough Strategy of the 21st Century"**. Motorola was the birthplace of Six Sigma in the mid 80s. Twenty-five years later, the D.M.A.I.C. philosophy has been incorporated into businesses through our economy. What makes Six Sigma different from other QI processes and how can this traditional manufacturing stragegy be applied to healthcare? This session will provide the answers.

Marguerite Busch, Compliance Officer for Pathology Associates Medical Laboratories in Spokane, will present a session entitled **"HIPAA Compliance Update – What is New, Different, or Still in Transition".** During 2002, a number of changes have been communicated regarding HIPAA implementation. This presentation will cover key points concerning implementation/enforcement dates, consents, business associate agreements, and security provisions.

The Conference will also provide updates on bioterrorism preparedness activities in Washington as well as on the activities of the Clinical Laboratory Personnel Shortage Workgroup.

LOCATION: The Conference this year will be held at the Seattle Marriott Sea-Tac Airport with easy access from Interstate 5 and the airport. Conference programs and registration information were mailed in mid-September. If you did not receive your Conference Registration Flyer or have questions, contact information is found on page 2. The registration fee will be $90 per person and will include a continental breakfast, breaks, and lunch. MAKE YOUR PLANS TO ATTEND TODAY!!

Inside This Issue

Practice Guidelines

The following practice guidelines have been developed by the Clinical Laboratory Advisory Council. They can be accessed at the following website:
www.doh.wa.gov/hsqa/fsl/LQA_Home.htm

Anemia	Point-of-Care Testing
ANA	PSA
Bleeding Disorders	Renal Disease
Chlamydia	STD
Diabetes	Thyroid
Hepatitis	Tuberculosis
HIV	Urinalysis
Lipid Screening	Wellness

Gonorrhea Test Kits Recall Notice

The following information is taken from a Recall Notice Press Release issued by the Food and Drug Administration on August 30, 2002.

The Food and Drug Administration (FDA) today announced that Abbott Laboratories, Inc., has initiated a worldwide recall of 32 laboratory kits used to diagnose gonorrhea. The kits have been shown to be unreliable because they may give false negative results. These test kits were distributed to hospitals and laboratories from January 11 to June 24, 2002.

Abbott notified its customers (clinical laboratories) to discontinue use of all test kits and to destroy any remaining product. Abbott also advised the laboratories to contact the health care providers served by their facility and have them determine if their patients need to be re-tested. The physician should offer a re-test to the patients whose test results were negative and who were not already treated. Repeat testing should be performed on a fresh specimen and not on retained specimens. Abbott Laboratories will reimburse expenses associated with repeat testing.

Abbott voluntarily recalled 32 lots of its gonorrhea test kits after learning through routine internal testing that certain lots did not meet specifications and, as a result, could report positive test results as negative. Upon further testing, Abbott determined that only 16 of these 32 lots did not meet internal release criteria. Abbott is continuing to investigate the cause of the problem.

The 16 lots that failed to meet specification when tested by Abbott are 84073M400; 84075M400; 84142M300; 84146M300; 85487M200; 87007M400; 87103M400; 87243M100; 87377M200; 87899M200; 87905M200; 88097M300; 88105M300; 88107M300; 88439M200; and 88439M201. Laboratories with questions can contact Abbott Laboratories at 1-800-527-1869. Physicians with questions should contact Abbott Laboratories at 1-866-233-0471.

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LQA home page: http://www.doh.wa.gov/lqa.htm
PHL home page:
http://www.doh.wa.gov/EHSPHL/PHL/default.htm

TB Reporting Change for Laboratories Effective 9/13/2002

REPORT ALL
PRESUMPTIVE AND CONFIRMED
LABORATORY RESULTS OF
Mycobacterium tuberculosis
within two (2) days to:

Phone: (206) 361-2838
Fax: (206) 361-2932
Address: DOH TB Laboratory
1610 NE 150th Street
Shoreline, WA 98155

see article on page 3

Notifiable Conditions Tuberculosis Reporting Change

by Washington State Department of Health (DOH) Tuberculosis(TB) Program/Services

The DOH TB Program/Services is in the process of transferring the reporting of laboratory positive smear/culture results from the TB Program in Olympia to the Public Health Laboratory (PHL) in Shoreline, WA. Effective September 13, 2002, the following changes will apply:

Laboratories: Reports of positive AFB smears and TB isolates will be taken by the PHL, and will no longer be the responsibility of the DOH Olympia TB Program.

NOTE: Cases of confirmed or suspected TB should continue to be reported to the Olympia TB Program per:
WAC 246-101-010 Definitions within the notifiable conditions regulations. The following definitions apply in the interpretation and enforcement of this chapter:

(4) "Cases" means a person, alive or dead, diagnosed with a particular disease or condition by a health care provider with diagnosis based on clinical or laboratory criteria or both.

This will require changes to the WAC Notifiable Conditions poster/chart originally published for Washington State laboratories. This change will require modification of the poster as follows: the telephone number given for reporting of *Mycobacterium tuberculosis* in the code legend in the bottom left hand side of the poster should be changed to:
&iii Notifiable to DOH – PHL (206) 361-2838.

Currently the *Notifiable Conditions & Washington's Laboratories* poster/chart lists the Olympia TB program phone number for reporting suspected TB specimens. The transfer of reporting duties will result in a change in mail, phone and fax numbers.

The new PHL numbers are: phone (206) 361-2838 and fax (206) 361-2932.

A letter of notification has been mailed and faxed to the TB Core Labs and other laboratories that perform tests on AFB positive specimens as well as all local health departments.

Content of documentation accompanying specimen submission (WAC 246-101-215):

- Type of specimen tested
- Name of reporting laboratory
- Telephone number of reporting laboratory
- Date specimen collected
- Requesting health care provider's name
- Requesting health care provider's phone number or address, or both
- Test result
- Name of patient (if available), or patient identifier
- Sex of patient (if available)
- Date of birth of patient (if available)
- Address of patient (if available)
- Telephone number of patient (if available)
- Other information of epidemiological value (if available)

Each laboratory should prepare a subculture to be retained for its own use, and send the original isolate to the PHL. The PHL can accept either liquid or solid media.

Content of notifications for positive cultures or preliminary test results (WAC 246-101-225):

- Date specimen collected
- Source of specimen tested
- Date specimen received by reporting laboratory
- Test result
- Submitter accession number
- Name of reporting laboratory
- Telephone number of reporting laboratory
- Requesting health care provider's name
- Requesting health care provider's phone number or address, or both

Client Information:
Name of patient (if available) or patient identifier; sex of patient (if available); date of birth or age of the patient (if available).

Waived Testing Helpful Hints

Ten good laboratory practices (GLP) were listed in this column in the August 2002 issue of *Elaborations.* We will discuss each GLP in the next several issues.

GLP: Have the correct request and collect a good specimen

- Be sure that you know exactly what test the provider ordered before proceeding with the test;
- Assure that the patient sample is collected properly;
- Give clear, concise, oral or written instructions;
- Inform the patient of any test preparation such as fasting, clean catch urines, etc.

Remember that the quality of the test result can only be as good as the specimen collected!

NOTE: Check this spot in future editions of Elaborations for more helpful hints with waived testing.

Calendar of Events

PHL Training Classes:

Waived Tests Training Module 1: Urine Dipstick

October 5	Shoreline
October 12	Spokane

Urine Sediments

October 9	Shoreline
October 10	Shoreline

Northwest Medical Laboratory Symposium

October 16 - 19	Portland

9th Annual Clinical Laboratory Conference

November 11	Seattle

Contact information for the events listed above can be found on page 2. The Calendar of Events is a list of upcoming conferences, deadlines, and other dates of interest to the clinical laboratory community. If you have events that you would like to have included, please mail them to ELABORATIONS at the address on page 2. Information must be received at least one month before the scheduled event. The editor reserves the right to make final decisions on inclusion.

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